

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

JUN 11 2001

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO,

Plaintiff,

vs.

Cause No.: CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual;

Defendants.

**THE REGENTS OF THE UNIVERSITY OF NEW MEXICO'S
PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

Plaintiff The Regents of the University of New Mexico ("University") hereby submits its proposed Findings of Fact and Conclusions of Law for this Court's consideration in connection with the trial set on June 25, 2001.

Findings of Fact

1. The Plaintiff University is a body corporate established under the Constitution and Laws of the State of New Mexico.
2. The Defendant Galen D. Knight ("Knight") is a resident of the State of New Mexico, and the Defendant Terence J. Scallen ("Scallen") is a resident of the State of California.
3. This matter was tried on the sole issue of ownership of certain patents and patent

285

applications as alleged in Count I of the Complaint and determination and correction of inventorship of certain specified patents as alleged in Count III.

4. The Court has entered summary judgment in favor of the Plaintiff on Count II of the Complaint, holding that the University is the owner of all right, title, and interest to the Beta-Alethine Patents and Applications (as defined in the Amended Complaint). The Court has also entered summary judgment on Count IV, holding that Knight and Scallen breached their contractual obligations with the University by failing to execute assignments to the Vitaletheine Patents and Applications and Beta-Alethine Patents and Applications (as such terms are defined in the Amended Complaint). The Court has also entered summary judgment that the Defendants are the only joint inventors of one of the Vitaletheine Issued Patents, U.S. Patent No. 5,370,868 (Count III).
5. Counts V through VII of the Complaint were dismissed on the motion of Plaintiff University.
6. Count III of the Amended Complaint arises under 35 U.S.C. § 256 and 28 U.S.C. § 2201.
7. The allegations of Counts I and III raise and allege issues that arise under the Patent Laws (35 U.S.C. § 1 et seq.).
8. The patent application (Serial No. 08/317,548) that matured into United States Patent No. 5,578,313 (the “‘313 Patent”), entitled “Therapeutic Uses of Vitaletheine Modulators in Neoplasia”, was filed on October 4, 1994, as a divisional application of Application Serial No. 07/928,725, filed on August 12, 1992. The ‘313 Patent issued

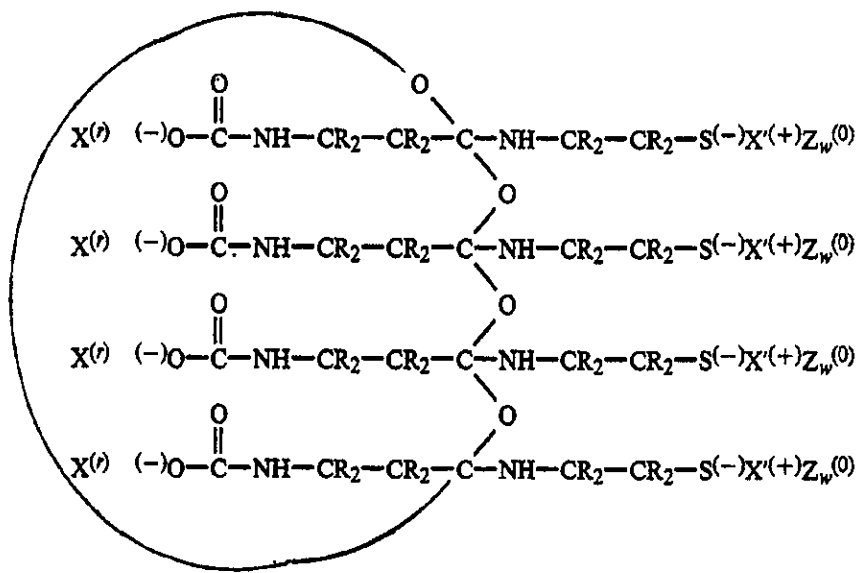
on November 26, 1996, with Knight and Scallen listed as inventors. Both Knight and Scallen signed a declaration of inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.

9. The patent application (Serial No. 08/463,732) that matured into United States Patent No. 6,096,536 (the “‘536 Patent”), entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxo Beta-Alanyl-Taurine”, was filed on June 5, 1995, as a continuation application of a divisional application of United States Application Serial No. 07/941,926. The ‘536 Patent issued on August 1, 2000, with Knight and Scallen listed as inventors. Both Knight and Scallen signed a declaration of inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/941,926.
10. United States Patent Application Serial No. 08/463,784 (the “‘784 Application”), now entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxo Beta-Alanyl-Taurine”, was filed on June 5, 1995, as a continuation application of a divisional application of Application Serial No. 07/941,926, with Knight and Scallen listed as inventors and is pending before the United States Patent and Trademark Office (“USPTO”). Both Knight and Scallen signed a declaration of inventorship as to Application Serial No. 07/941,926.
11. United States Patent Application Serial No. 08/466,143 (the “‘143 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892,

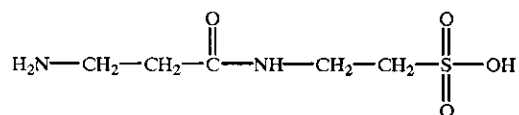
with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of inventorship as to United States Application No. 07/910,892.

12. United States Patent Application Serial No. 08/469,697 (the “697 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of inventorship as to United States Application No. 07/910,892.
13. In the ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application the University, as the putative owner of the inventions that are the subject matter of these patents and applications, made certain amendments to the molecular structure of certain compounds disclosed and claimed in the specifications thereof. These amendments were made subsequent to filing of the application for each of the foregoing patents and applications during the ordinary course of presentation of the applications. (The amendments made to the molecular structure of the compounds in each application, are, with respect to the change to the chemical structure, each referred to as the “Amendment”. The ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application are collectively referred to herein as the “Patents and Applications”).
14. The Amendment to the Patents and Applications relates to a compound incorrectly

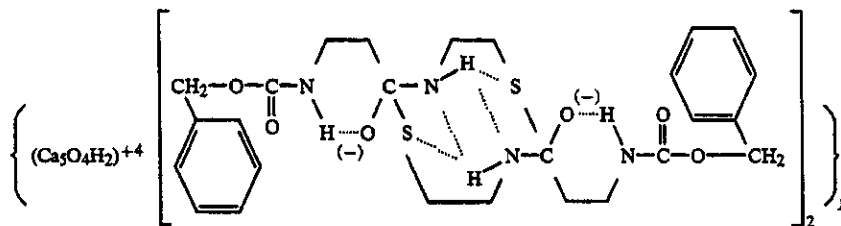
named in the Patents and Applications as filed as "vitaletheine V₄." The molecular structure contained in the Patents and Applications as filed was:



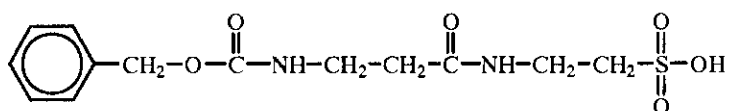
In the Amendment in each Patent and Application, the foregoing molecular structure was corrected with the following molecular structure (the "beta-alanyl-aurine Amendment"):



15. The Amendment to the Patents and Applications also relates to a compound incorrectly named in the Patents and Applications as the "benzyl derivative of vitaletheine." The molecular structure contained in the Patents and Applications as filed was:



In the Amendment in each Patent and Application, the foregoing molecular structure was corrected to the following molecular structure (the “carbobenzoxy beta-alanyl-taurine Amendment”):



16. In the ‘313 Patent, the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
17. In the ‘536 Patent, the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
18. In the ‘784 Application, which has not yet issued as a patent, the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment were accepted by the USPTO in the claims following an initial rejection based on new matter.
19. In the ‘143 Application, which has not yet issued as a patent, the beta-alanyl-taurine

Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in the claims following an initial rejection based on new matter.

20. In the '697 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
21. The molecular structure disclosed in the beta-alanyl-aurine Amendment is implicit in and an inherent characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.
22. The molecular structure disclosed in the carbobenzoxy beta-alanyl-aurine Amendment is implicit in and an inherent characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.
23. The molecular structure disclosed in the beta-alanyl-aurine Amendment represents the true and correct compound resulting from the synthetic process for "vitaltheine V₄" disclosed in the Patents and Applications as filed.
24. The molecular structure disclosed in the carbobenzoxy beta-alanyl-aurine Amendment represents the true and correct compound resulting from the synthetic process for the "benzyl derivative of vitaltheine" disclosed in the Patents and Applications as filed.
25. In each of the '536 Patent, the '784 Application, the '143 Application, and the '697 Application, protests were filed by defendant Galen Knight; the protests appear in the prosecution history file of each Patent and Application. These protests included the

same new matter arguments now raised by defendants Knight and Scallen with respect to the beta-alanyl-aurine Amendment and the carbobenzoxv beta-alanyl-aurine Amendment. Since the protests are a part of the official prosecution history file, they were presumptively considered by the Examiners in the USPTO.

26. A total of three different Examiners of the USPTO, each skilled in the relevant technology, have considered and accepted the beta-alanyl-aurine Amendment and the carbobenzoxv beta-alanyl-aurine Amendment as properly filed and as containing subject matter that was not new or in contravention of the Patent Laws.
27. No amendment was made to the specification of the application maturing into U.S. Patent No. 5,370,868 that altered the molecular structure of any compound disclosed in the application as filed.
28. Hauser Chemical Research, Inc. ("Hauser") was retained by Dovetail Technologies, Inc. ("Dovetail"), the licensee of the University, to synthesize certain compounds including vitalethine, vitaletheine V₄, and benzyl derivative of vitaletheine for use in preclinical studies and clinical trials by Dovetail. Hauser performed numerous syntheses, some of which were exactly in accordance with the methods described in the Patents and Applications. The compounds that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V₄ did not have the molecular structures assigned to these compounds by the inventors in the Patents and Applications as filed. The compound called "Vitaletheine" could not be synthesized.
29. The University retained an expert consulting firm, Professional Analysis, Inc. ("PAI"),

one of whose employees was located in Albuquerque, to synthesize and characterize the compounds produced in accordance with the methods described in the Patents and Applications. Several suggestions were given to the PAI employee during the course of the attempts to synthesize the compounds by Knight, one of the inventors. Following the methods described in the Patents and Applications, the compounds called vitalethine V₄, and the benzyl derivative of vitalethine were synthesized, but did not have the molecular structure depicted in the Patents and Applications.

30. The criticisms and alleged defects in the syntheses performed by Hauser and PAI advanced in the protests filed by the inventors during pendency of the Patents and Applications, and reiterated during the course of this lawsuit, including the trial, were either scientifically incorrect or failed to identify any deviation from the method described in the Patents and Applications that would result in a different compound and thus did not invalidate the syntheses as proof that the chemical structures as assigned in the applications as filed was incorrect.
31. Knight admitted that he was the only person in the world that had successfully synthesized the product called and described as "vitalethine" in the Patents and Applications. Doubt was cast on the claims of the inventors that a compound exists with a molecular structure as assigned in the Patents and Applications for vitalethine because the inventors did not preserve any of the alleged vitalethine compound.
32. The University has proved by a preponderance of the evidence that following the method for vitalethine V₄ and the benzyl derivative of vitalethine, the correct chemical

name of the compounds produced were beta-alanyl-aurine and carbobenzoxy beta-alanyl-aurine, respectively, and the correct molecular structures are as shown in the Amendments. The University has proved by a preponderance of the evidence that the method for synthesizing vitaethine as described in the Patents and Applications, when followed, will yield the same product with which the process began, namely, beta-alethine. Beta-alethine was well-known in the art long prior to the making of the inventions resulting in the Patents and Applications.

33. By a preponderance of the evidence, the facts at trial establish that the Examiners and the USPTO were correct in accepting the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment and that such amendments assign a molecular structure that is inherent in the compounds synthesized using the method described in the Patents and Applications.
34. As determined by the Court in entering summary judgment as to Count IV, Knight and Scallen breached their contractual obligations to the University by failing to execute assignments to the Vitaethine Patents and Applications. The University is the true and lawful owner of U.S. Patent No. 5,370,868, as to which no amendment to the molecular structure of any compound therein was made. The University is also the true and lawful owner of all other Patents and Applications included within the Vitaethine Patents and Applications as to which no amendment was made as to the molecular structure of any compound included therein.

Conclusions of Law

1. The Court has personal jurisdiction over the parties.
2. Venue is properly laid in the District of New Mexico pursuant to 28 U.S.C. § 1391(b).
3. The rights of Plaintiff University to relief necessarily depend on resolution of one or more substantive questions of United States Patent Law.
4. The relief sought by Plaintiff University in Count III pursuant to 35 U.S.C. § 256 necessarily arises under the United States Patent Law for which federal courts have exclusive jurisdiction.
5. This Court has subject matter jurisdiction over the claims now pending.
6. The last sentence of 35 U.S.C. § 132 provides as follows: “No amendment shall introduce new matter into the disclosure of the invention.”
7. Determination of whether an amendment introduces new matter “depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter.” Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1993).
8. If new matter is introduced during prosecution of a patent application, then claims depending on or incorporating such new matter are invalid under 35 U.S.C. § 112, ¶ 1. Waldmar Link, GmbH & Co. v. Osteonics Corp., 32 F.2d 556, 558 (Fed. Cir. 1994); Transco Prod., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558 (Fed. Cir. 1994); SDS USA, Inc. v. Ken Specialties, Inc., 122 F.Supp.2d 533, 544 (D.N.J. 2000).

9. A patent is presumed valid. 35 U.S.C. § 282.
10. A determination by the Patent and Trademark Office that an amendment does not introduce “new matter” as defined in 35 U.S.C. § 132 is entitled to an especially weighty presumption of correctness:

Whether particular technological information is "new matter" depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter. A patent is presumed valid, and this presumption is based in part on the expertise of the patent examiners presumed to have done their job. This presumption, which may be viewed as a presumption of administrative correctness, as applied to a new matter determination was discussed by our predecessor court, which stated that "the fact that the Patent Office allows . . . an amendment without objection thereto as new matter (within the meaning of 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness."

Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d 1555 at 1574-75 (Fed. Cir. 1993); accord, In re Smythe, 480 F.2d 1376, 1385 n. 5, (CCPA 1973); Technicon Instruments Corp. v. Coleman Instruments, Inc., 255 F.Supp. 630 (N.D.Ill. 1966), aff'd, 385 F.2d 391 (7th Cir. 1967).

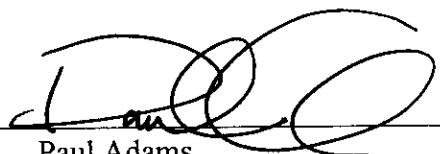
11. The rule applied is “that a structural formula may be corrected without violation of 35 USC § 132, if ‘there is sufficient evidence in the record to show the (proposed structure) to be an inherent characteristic of the subject matter so identified’”, Ex parte Marsili, 214 U.S.P.Q. 904, 906 (B.P.A.I., 1979), quoting from In re Magerlein et al., 52 CCPA 1637, 1640, 346 F.2d 609 (1965).

12. The chemical compounds described in the beta-alanyl-aurine Amendment and the carbobenzoy beta-alanyl-aurine Amendment inherently had, when the Patents and Applications were filed, and now have the molecular structures given in the Amendments. “[T]he products described, exemplified and claimed . . . inherently had and have now the structure given in the amendment in question.” Ex parte Marsili, 214 U.S.P.Q. at 906.
13. The Amendments do not, as a matter of law, introduce “new matter” into the Patents and Applications in contravention of 35 U.S.C. § 132.
14. The Defendants Knight and Scallen are the properly named and sole inventors of the Patents and Applications as amended.
15. The Plaintiff University is the true and lawful owner of all right, title and interest to the Patents and Applications, including the ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional application of any of the foregoing, or which is a continuation or divisional application of a predecessor of any of the foregoing.
16. The Defendants Knight and Scallen are the only, joint and properly named inventors of the ‘313 Patent and the ‘536 Patent.
17. The Defendants Knight and Scallen are the only, joint and properly named inventors of the inventions disclosed in the ‘784 Application, the ‘143 Application, and the ‘697 Application, including without limitation the Amendments.

18. The Plaintiff University is the true and lawful owner of all right, title and interest to U.S. Patent No. 5,370,868, as to which no amendment to the structure of any compound therein was made, and all other patent applications included within the Vitaletheine Patents and Applications as to which no amendment was made as to the structure of any compound included therein.

Dated this 11th day of June, 2001.

PEACOCK MYERS & ADAMS, P.C.

By: 

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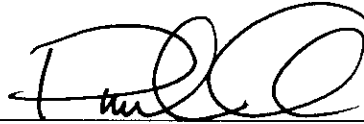
ATTORNEYS FOR PLAINTIFF THE REGENTS
OF THE UNIVERSITY OF NEW MEXICO

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing pleading was sent via first class mail this 11th day of June, 2001 to the following:

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Albuquerque, NM 87110-1640

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